IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC., Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC, Defendants.	C.A. No. 21-1694-JLH **JURY TRIAL DEMANDED**
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA, Counterclaim Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC., Counterclaim Defendants/Reply Plaintiffs.	

UMN/FINCH'S MOTION FOR JUDGMENT AS A MATTER OF LAW

I. INTRODUCTION

UMN/Finch respectfully move for judgement as a matter of law ("JMOL") under Federal Rule of Civil Procedure 50(a) with respect to infringement, validity, and damages. The evidence presented at trial cuts decisively in UMN/Finch's favor. Based on that evidence, no reasonable jury could find against UMN/Finch on any of their claims in this case. The Court should therefore enter JMOL for UMN/Finch on every issue.

II. LEGAL STANDARD

JMOL is appropriate "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a).

III. ARGUMENT

A. Ferring Directly Infringes the Asserted Claims of the '080 Patent.

1. Claims 2 and 9 of the '080 Patent.

UMN/Finch presented overwhelming evidence that REBYOTA literally meets every limitation of claims 2 and 9 of the '080 Patent. Ferring did not dispute this. The claims require: an enema delivery system including a sealed container, delivery tubing, and a pharmaceutical composition comprising a microbiota suspension comprising a cryoprotectant and viable uncultured non-pathogenic bacteria from prescreened human donor stool that is stable during long term storage when frozen (independent claim 1); and wherein the system protects the bacteria from destruction when frozen or exposed to air (claim 2), or wherein the composition further comprises an antioxidant (claim 9). *See* JTX-6 ("'080 Patent"), cls. 1, 2, 9.

UMN/Finch's experts, Drs. Benson and Park, established that each limitation of claims 2 and 9 are met by REBYOTA. Common to both claims, Drs. Benson's and Park's testimony was also supported by Ferring's FDA submissions, which included: **(1)** the label for REBYOTA that describes REBYOTA's packaging and overall composition, including that it is manufactured from a combination of PEG, saline, and stool of human donors that are prescreened for pathogens (PTX-117.3, .6); and **(2)** stability data showing that REBYOTA is stable during long-term storage (PTX-929.7, .23). *See* 08/06/24 Trial Tr. at 91:9-94:14; *see generally* PTX-117 (REBYOTA label describing delivery system, composition, and storage instructions); PTX-929.7, 23 (describing frozen storage). For claim 2, Dr. Benson further explained that the REBYOTA packaging is a sealed container that protects the suspension when frozen or exposed to air, which was again

supported by Ferring's own FDA submissions. 08/06/24 Trial Tr. at 94:15-95:12; PTX-139.33, 43. And for claim 9, the evidence confirms there are two antioxidants in REBYOTA. First, Dr. Park testified that REBYOTA includes butylated hydroxytoluene ("BHT") in amounts sufficient to act as an antioxidant. 08/06/24 Trial Tr. at 39:12-43:8; *id.* at 95:19-24 (Benson's testimony); PTX-117; PTX-1173.196; PTX-4296.1. Second, Dr. Park testified that PEG—which is present in REBYOTA—is an antioxidant. 08/06/24 Trial Tr. 45:18-19. This evidence overwhelmingly establishes each element of the asserted claims is literally present in REBYOTA, and therefore that Ferring directly infringes these claims.

Ferring disputed none of this evidence, elicited no evidence undermining any of Finch's evidence, and presented no evidence of its own that REBYOTA does not practice the asserted claims. Ferring's only expert to opine on infringement, Dr. Johnson, explicitly confirmed that he had no noninfringement opinions for the '080 patent. 08/07/24 Trial Tr. at 176:1-4. Under such circumstances, no reasonable jury could find that Ferring does not infringe claims 2 and 9 of the '080 patent and JMOL of infringement should be entered.

2. Claims 16 and 21 of the '309 Patent.

For many of the same reasons, the evidence also establishes Ferring infringes claim 16 and 21 of the '309 Patent, which require: a transportable enema delivery product comprising flexible delivery tubing, a sealed bag, and a pharmaceutical composition within the bag comprising a saline, cryoprotectant, and suspension of viable uncultured non-pathogenic fecal bacteria from human donor stool that are separated from rough particulate matter, wherein the composition is in an amount effective for treating rCDI (independent claim 12); and wherein the cryoprotectant comprises PEG (claim 16), or wherein the composition further comprises an antioxidant (claim 21). *See* JTX-4 ("'309 Patent"), cls. 12, 16, 21.

Drs. Benson, Stollman, and Park testified, together with supporting evidence, including Ferring's FDA submissions, that REBYOTA meets every limitation of claims 16 and 21. *See* 08/06/24 Trial Tr. at 91:9-94:14, 96:18-101:14 (Benson testimony); *id.* at 21:7-24:9 (Stollman testimony explaining why REBYOTA is effective for treating recurrent *C. difficile* infection);[1] 08/05/2024 Trial Tr. at 290:13-293:1 (Bancke confirming REBYOA is an effective treatment for rCDI); 08/06/2024 Trial Tr. at 28:15-30:18 (similar); *id.* at 101:21-102:9 (Benson testimony on PEG); *id.* at 39:12-43:8, 45:18-19 (Park testimony on antioxidant); *see also supra* § III.A.1 (citing evidence).

Ferring did not dispute—and thus effectively conceded—that REBYOTA practices all but one limitation of claims 16 and 21: the "fecal bacteria are separated from rough particulate matter" limitation found in unasserted independent claim 12. As Dr. Benson explained, together with other supporting evidence, the purpose and effect of passing the fecal microbiota suspension through a 0.5 mm sieve (the stomacher) during REBYOTA's manufacture is to separate the fecal bacteria from rough, macroscopic, non-living matter. 08/06/2024 Trial Tr. at 67:25-79:17; 08/08/24 Trial Tr. 207:21-24; PTX-117.8; PTX-255.6, .7; PTX-248.3. No reasonable juror could find for Ferring on this point. Ferring argued that REBYOTA contains fecal bacteria that are not "separated from rough particulate matter"[2] because it allegedly contains a trivial amount of rough particulate

[1] UMN/Finch presented a mountain of evidence—including Ferring's own descriptions of its clinical trials and statements to the FDA—that REBYOTA is effective for treating rCDI. *See, e.g.*, 08/06/2024 Trial Tr. at 21:20-28:14 (Stollman); PTX-117.9 (discussing measured rates of "treatment success" in REBYOTA clinical trials); PTX-118.3 (describing Ferring Phase 3 clinical trial for demonstrating the efficacy of REBYOTA "for the Treatment of Recurrent *Clostridium difficile* Infection"); PTX-604 (Ferring website touting REBYOTA as safe to "treat" rCDI); PTX686.7 (recommending FMT as "treatment" for rCDI); PTX-1690.2 (REBYOTA is "effective and safe in treating patients with" rCDI); PTX-1632 at 1:25:55-1:26:16 (Rebiotix Head of Clinical Development stating at FDA open session that REBYOTA "demonstrated efficacy for the treatment" of rCDI).

[2] The Court construed "rough particulate matter" to mean "rough, macroscopic, non-living matter." D.I. 145 at 2.

matter. 08/07/24 Trial Tr. at 167:9-173:22. But even he agreed that the claims are satisfied if there are a minimal number of particles that do not pass through a 0.5 mm sieve. *Id.* at 180:13-182:15. And he conceded that rough particulate matter remained in the strainer bag and was therefore separated from the fecal bacteria. *Id.* at 205:23-207:24. Thus, even if the claims required complete separation of rough particulate matter (they do not), Ferring would still infringe.

Accordingly, JMOL should be entered that Ferring induces infringement of claims 16 and 21 of the '309 Patent.

B. Ferring Induces Infringement of Claim 7 of the '914 Patent.

The evidence further establishes that Ferring induces infringement under 35 U.S.C. § 271(b). Liability for induced infringement attaches when (1) there is an underlying act of direct infringement and (2) the alleged inducer took affirmative acts with the specific intent to encourage the direct infringement. *See, e.g.*, *Minnesota Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1305 (Fed. Cir. 2002) (affirming JMOL of induced infringement where defendant was aware of the asserted patents and supplied the infringing products to customers "with instructions … which, when followed, would lead to infringement"); *see also Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017). These elements are met here. As explained below, the evidence establishes that (1) physicians administering REBYOTA directly infringe claim 7 of the '914 Patent and (2) Ferring engages in affirmative acts with the specific intent to encourage that infringement. Accordingly, JMOL should be entered that Ferring induces infringement of claim 7 of the '914 Patent.

1. UMN/Finch Have Established Direct Infringement and No Reasonable Jury Could Conclude Otherwise.

UMN/Finch adduced overwhelming evidence at trial of direct infringement of claim 7 of the '914 patent, both literally and under the doctrine of equivalents. Drs. Stollman and Benson testified that REBYOTA meets each limitation of claim 7, which recites a method of administering

a pharmaceutical composition wherein the composition: (1) is administered to patients in an effective amount; (2) is a fecal extract comprising a fecal donor's intestinal microbiota; (3) is capable of passing through a 0.5 mm sieve; (4) comprises a pharmaceutically acceptable carrier (saline); (5) includes fecal microbiota from at least six of the required bacterial classes; (6) reduces the relative abundance of proteobacteria by at least 10%; and (7) increases the fecal microbiota diversity of the patient. 08/06/24 Trial Tr. at 58:23-72:18 (Benson); *id.* at 21:7-24:9 (Stollman); PTX-117.8; PTX-176.2; PTX-136.66; PTX-361; PTX-140.6. The administration of REBYOTA thus literally practices each step of the method of claim 7.

At trial, Ferring presented just one non-infringement defense: that REBYOTA is not "capable of passing through a 5 mm sieve." But the evidence conclusively demonstrated that is simply not the case—REBYOTA contains fecal extract that is not only capable of passing through a 0.5 mm sieve, ***that is precisely how REBYOTA is prepared during manufacture***. *See, e.g.*, 08/06/24 Trial Tr. at 67:5-72:18, 90:7-91:7; PTX-140.6 (FDA Submission for REBYOTA noting the strainer bag "has a pore size of approximately 0.5 mm through which the product is strained"); PTX-298.1, 2 (Ferring/Rebiotix internal email identifying important language to "avoid potential patent infringement issues" as the "strainer bag has a pore size of approximately 0.5 mm through which the product is strained"); PTX-940 (strainer bag manufacturer listing 0.5 mm pore size); PTX-139.27; PTX-217.

Ferring's non-infringement defense hinged on the misconception that to meet the "capable of passing through a 0.5 mm sieve" limitation, an extract must not contain ***any*** particles exceeding 0.5 mm and that REBYOTA does not infringe because tests performed by its expert, Dr. Johnson, purportedly show that small amounts of REBYOTA did not pass through a 0.5 mm sieve. That argument fails for multiple reasons.

First, it is inconsistent with basic principles of claim construction. Claim 7 of the '914 Patent requires a composition that *comprises*—and therefore, under black letter law, *includes but is not limited to*—a fecal extract capable of passing through a 0.5 mm sieve. *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005). ***Second***, it is inconsistent with the doctrine of claim differentiation, which presumes that "different words used in different claims result in a difference in meaning and scope for each of the claims." *Clearstream Wastewater Sys., Inc. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1446 (Fed. Cir. 2000). In particular, Ferring's interpretation improperly gives "capable of passing through a 0.5 mm sieve" the same meaning as the "no particle having a size greater than 0.5 mm" limitation of unasserted claim 18, even though the claims use different language. ***Third***, it is inconsistent with Dr. Johnson's (and Dr. Benson's) own understanding of the scope of the claim, which allows for the presence of "minimal" particles that do not pass through a 0.5 mm sieve. 08/06/24 Trial Tr. at 74:8-18; 08/07/24 Trial Tr. at 182:3-15 (Johnson impeachment). And, as Dr. Benson testified (and Dr. Johnson conceded during cross examination), Dr. Johnson's tests at best showed that only a minimal amount of REBYOTA did not pass through the 0.5 mm sieve, *id.* at 73:8-74:7; 08/07/2024 at 184:6-188:13. ***Fourth***, Dr. Benson explained that the trivial amount of REBYOTA that did not pass through the sieve used in Dr. Johnson's tests was the chance result of the orientation and clumping of particles, rather than their size, and that those particles are in fact capable of passing through a 0.5 mm sieve. 08/06/24 Trial Tr. at 74:23-79:17. ***Fifth***, Dr. Benson further testified that, even if this limitation is not literally practiced, it is met under the doctrine of equivalents because the amount of particles allegedly incapable of passing through a 0.5 mm sieve is insubstantial and does not prevent REBYOTA from performing substantially the same function in substantially the same way with substantially the same results as the claimed composition. *Id.* at 80:5-81:17. Dr. Johnson had no opinion to the contrary. 08/07/24 Trial Tr. at 193:10-21.

2. Ferring Actively Induces Infringement of Claim 7 of the '914 Patent.

The trial record also establishes that Ferring actively induces physicians to infringe claim 7 by administering REBYOTA to treat rCDI. "[S]pecific intent may be inferred from circumstantial evidence where a defendant has both knowledge of the patent and specific intent to cause the acts constituting infringement." *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1342 (Fed. Cir. 2008). The required intent to cause the acts constituting infringement may be shown through product labeling and marketing instructing or encouraging a direct infringer to practice the patented method. *See, e.g.*, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021). Likewise, the defendant's "role as the designer and manufacturer" of an infringing product "may evidence an intent sufficient specific to support a finding of inducement." *Ricoh*, 550 F.3d at 1343. As can the defendant's employment of an individual with knowledge of the patented design and statements indicating the defendant relied on the employee's knowledge. *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1222 (Fed. Cir. 2006) (sustaining jury verdict of active inducement under 271(f)). The evidence establishes that ***all*** of these indicia of intent are present here.

First, it is undisputed that Ferring was aware of the '914 Patent. 08/06/24 Trial Tr. at 47:14-16; *id.* at 275:8-16. Indeed, as the trial record clearly established, as a result of Lee Jones' and Rebiotix's egregious copying of UMN's inventions, including from UMN's then-confidential and subsequently published patent applications and other technical information, to develop REBYOTA, Ferring has been aware of the '914 Patent's salient disclosures since well-before it issued. *See, e.g.*, 08/05/24 Trial Tr. at 265:15-270:12 (Jones); 08/05/24 Trial Tr. at 255:14-268:1 (Berman testimony regarding Ed Hlavka's interactions with UMN); *id.* at 83:13-88:12 (Benson); PTX-170 (Rebiotix email discussing Ms. Jones' awareness of the provisional application that ultimately led to the '914 Patent); PTX-298.1 (Rebiotix email noting need to use certain language

to "avoid potential patent infringement issues"). Additionally, as Dr. Benson explained, the information provided in Ferring's FDA submissions, clinical trial descriptions, and REBYOTA's label all show that Ferring should have and did know that individuals administering REBYOTA were infringing. 08/06/24 Trial Tr. at 82:13-83:12.

Second, Ferring takes a variety of affirmative acts with the intent to cause the infringing acts, including by instructing and encouraging healthcare providers to administer REBYOTA to treat rCDI in a manner Ferring knows will infringe. As Dr. Stollman explained, Ferring instructs and encourages physicians in a variety of ways to use REBYOTA in an effective amount in a patient in need thereof, including by: (1) providing a label with instructions for administration which, if followed, would infringe claim 7; (2) touting to physicians and the FDA REBYOTA's effectiveness for treating rCDI; and (3) instructing physicians to use insurance codes directed to the treatment of rCDI when they administer REBYOTA. 08/06/24 Trial Tr. at 24:10-31:8; PTX-117 (label); PTX-1632 at 1:25:55-1:26:16 (Bancke AdComm statement touting REBYOTA as effective for the treatment of rCDI); PTX-604.1, 3, 6 (Ferring web page advertising clinical data showing REBYOTA is safe and effective for treating rCDI and recommending REBYOTA for rCDI patients); PTX-376.3 (Ferring press release highlighting physician praise for treatment of rCDI using REBYOTA); PTX-608.1-2 (insurance billing codes).

Third, Ferring's and Rebiotix's reliance on the knowledge Ms. Jones copied from the '914 Patent inventors, Drs. Khoruts and Sadowsky, to design, develop, and manufacture REBYOTA is further evidence of Ferring's knowledge and intent to cause the infringing acts. *Ricoh*, 550 F.3d at 1325; *Liquid Dynamics*, 449 F.3d at 1222; PTX-40.1, PTX-42 (Ms. Jones' distributing UMN internal evaluation to Rebiotix employees); PTX-47 & PTX-48 (Ms. Jones noting that UMN article describing '914 Patent embodiments was "very helpful" to Rebiotix); PTX-80 & PTX-82 (former Rebiotix employee Ed Hlavka soliciting advice from '914 Patent inventors to develop

REBYOTA); PTX-419 (UMN invention disclosures produced by Ferring); 08/06/24 Trial Tr. 85:24-88:4; 08/05/24 Trial Tr. 195:23-197:23; 08/05/24 Trial Tr. 277:17-279:1; PTX-266 (REBYOTA was derived from Hamilton 2012, which is example 4 in the '914 patent). As does Ferring's insistence upon an indemnification clause in its merger agreement with Rebiotix that specifically identifies the applications that led to the '914 Patent. *See* PTX-56.57 (indemnification clause), 403 (identifying predecessor applications); 08/06/24 Trial Tr. at 204:19-205:12, 272:23-274:18; 08/07/24 Trial Tr. at 97:22-99:18. *Cf. SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1384 (Fed. Cir. 2013) (holding defendant's indemnification agreement with customers supported inference that defendant knew customers would perform infringing acts).

C. Ferring Contributes to Infringement of Claim 7 of the '914 Patent.

The evidence also shows that Ferring contributes to infringement of claim 7 by selling REBYOTA "for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use." 35 U.S.C § 271(c). As explained, the evidence decisively showed that Ferring manufactures and sells REBYOTA for use as a material part in the patented process of claim 7 knowing (indeed, intending) such use was patented and infringing. *See generally* Sections III.A, III.B, *supra*; *see also* 08/06/24 Trial Tr. at 88:13-17 (Dr. Benson testifying that REBYOTA is made for use in the patented process). The evidence further established that REBYOTA has no substantial noninfringing uses. As Dr. Stollman explained, REBYOTA's ***only*** substantial use is in its administration to patients for the treatment of rCDI. 08/06/24 Trial Tr. at 30:19-23. Ferring presented no evidence or argument to the contrary. Accordingly, JMOL should be entered that Ferring contributes to the infringement of claim 7 of the '914 Patent.

D. Ferring Willfully Infringes All of the Asserted Claims.

The evidence overwhelmingly confirms Ferring willfully infringes the '080, '309, and '914 claims. "[A] person having knowledge of an adverse patent has an affirmative duty to exercise due care to avoid infringement of a presumptively valid and enforceable patent." *SRI Int'l, Inc. v. Advanced Tech. Lab'ys, Inc.*, 127 F.3d 1462, 1464 (Fed. Cir. 1997). A finding of willfulness "requires a jury to find no more than deliberate or intentional infringement." *SRI Int'l, Inc. v. Cisco Systs., Inc.*, 14 F.4th 1323, 1330 (Fed. Cir. 2021). Moreover, an infringer's pre-issuance conduct is relevant to a finding of willfulness "[w]here there is particularly egregious behavior showing a party intent on misappropriating a competitor's proprietary technology." *Chimie v. PPG Indus., Inc.*, 218 F.R.D. 416, 422 (D. Del. 2003).

First, no reasonable juror could find that Ferring does not willfully infringe each of the asserted claims of the '080, '309, and '914 Patents. It is undisputed that Ferring has been aware of the '309 and '914 Patents since their issuance; the application that led to the '080 Patent since at least December 5, 2022; the PCT application that led to the '309 and '080 patents at least as early as November 2012, 08/06/24 Trial Tr. at 47:14-48:1; *id.* at 275:8-16; and the provisional application leading to the '914 patent in 2011, 08/07/24 Trial Tr. at 91:20-921:1 (discussing PTX-422). ***Second***, the evidence proves that Ferring egregiously copied the claimed invention of the '914 Patent before issuance and then studied the asserted patents after issuance knowing REBYOTA was copied from descriptions therein. *See* 08/05/24 Trial Tr. at 263:5-273:25. Indeed, Courtney Jones testified that the ideas used to develop REBYOTA were derived from the seminal 2012 paper co-authored by Drs. Sadowsky and Khoruts regarding the standardization procedures for preserving donor fecal samples used in FMT to treat rCDI. 08/07/24 Trial Tr. at 130:25-131:5' PTX-1717; PTX-266; PTX-217.

Third, the evidence shows unequivocally that Ferring knew that REBYOTA infringed, going so far as to adopt misleading language suggesting REBYOTA is made using an "approximately" 0.5 mm sieve to "avoid potential patent infringement issues." *See* 08/05/24 Trial Tr. at 274:9-275:5; PTX-298.2. Yet, despite all of this, Ferring deliberately continued to market and sell REBYOTA without making ***any*** changes to it to avoid the patent infringement issues of which Ferring was indisputably aware. *Id.* at 276:1-21; *see Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 492 (D. Del. 2019) (denying summary judgment of no willfulness where defendant failed to undertake efforts to design around). Ferring's awareness and lack of a subjective good faith belief it did not infringe is further demonstrated by its insistence that Rebiotix indemnify Ferring for infringement of the patents-in-suit. PTX-56.57 (indemnification clause), 403 (identifying predecessor applications); 08/06/24 Trial Tr. at 204:19-205:12; *cf. C R Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1380 (Fed. Cir. 2020) (reversing JMOL of no willfulness despite advice of counsel where defendant "was aware of the applications that issued as the patents-in-suit prior to their issuance" and "intentionally copied" plaintiff's product).

Under such circumstances, no reasonable juror could deny that Ferring's infringement "was either known or so obvious that it should have been known to the accused infringer." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 101 (2016) (internal quotation omitted).

E. The Asserted Claims are Valid.

1. Claims 16 and 21 of the '309 Patent Are Valid.

No reasonable juror could find claims 16 and 21 of the '309 patent would have been obvious over Hlavka,[3] the only allegedly invalidating prior art presented to the jury. Ferring did not dispute that Hlavka does not disclose at least (1) the claimed "cryoprotectant comprising

[3] The Hlavka reference was considered by the USPTO during prosecution of each of the Asserted Patents.

polyethylene glycol" of claim 16 or (2) the "antioxidant" of claim 21. To fill those gaps, Ferring appealed to the knowledge of a person of ordinary skill in the art ("POSA") but failed to provide clear and convincing evidence that "it would have been obvious to modify [Hlavka] to arrive at the patented invention." *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1363, 1367 (Fed. Cir. 2016). No reasonable juror could find that Ferring presented clear and convincing evidence it would have been obvious to modify Hlavka to supply these missing limitations. *Arendi*, 832 F.3d at 1367. Indeed, the evidence showed that Hlavka himself was experimenting with which cryoprotectant to use years after the date of his patent application. PTX-113. Accordingly, the Court should enter JMOL that Ferring has failed to carry its burden to prove invalidity.

First, Hlavka neither discloses nor renders obvious the use of PEG as a cryoprotectant, as required by claim 16. While Hlavka teaches the use of glycol cryoprotectants from amongst a list of other cryoprotectants, the evidence conclusively demonstrated it does not teach or suggest using ***polyethylene*** glycol as the cryoprotectant. As both parties' experts agreed, as of the date of the '309 Patent invention there were many glycols to choose from and no reason in the prior art to select PEG specifically. 08/06/24 Trial Tr. at 45:24-47:3; 08/07/24 Trial Tr. 282:22-24; 08/07/24 Trial Tr. 282:22-283:9; PTX-113. Dr. Britton's testimony that it nonetheless would have been obvious to select PEG from numerous candidates is based on nothing more than hindsight. *See Shire LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1307-1308 (Fed. Cir. 2015); *Cheese Systs., Inc. v. Tetra Pak Cheese and Powder Systs., Inc.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013).

Second, the evidence showed that the prior art not only did not suggest using PEG as a cryoprotectant in an FMT composition, it taught away from it. *See, e.g.*, *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1372-75, 1379-80 (Fed. Cir. 2000) (finding clear error in obviousness determination where there was a "history of prior art teaching away"); *St. Jude Medical, In. v. Access Closure, Inc.*, 729 F.3d 1369, 1381 (Fed. Cir. 2013) (affirming denial of JMOL where the

accused infringer used improper hindsight because the invention was against conventional wisdom). For example, the evidence showed that PEG was the active ingredient in a known laxative, MiraLAX. 08/7/24 Trial Tr. 288:5-10; 270:12-21. Indeed, Ferring's own argument from during prosecution of its patent application conceded as much, stating that PEG "is typically used to purge the gut and … is the active ingredient in some laxatives" and "[b]ecause of this, ***it would not be obvious*** to combine a substance that functions as a laxative to a microbiota restoration therapy composition." *See, e.g.*, 08/07/24 Trial Tr. 287:11-288:22; PTX-979; PTX-113.

Third, Hlavka does not teach or suggest the use of an antioxidant, as required by claim 21, and Ferring failed to provide clear and convincing evidence to the contrary. On this, the patent office and Dr. Britton agreed. 08/06/24 Trial Tr. at 278:25-281:11 (discussing claim 21 of the '309 and claims 2, 9 of the '080); 08/07/24 Trial Tr. at 280:10-13. And Dr. Britton was unable to identify any prior art that taught use of an antioxidant in an FMT composition or that a POSA would have motivated to add an antioxidant to an FMT preparation. *Id*. His opinion that it would have been obvious to do include an antioxidant nonetheless is classic hindsight.

Finally, as above, the jury was shown extensive evidence of objective indicia with a nexus to the '309 claims, including licensing, commercial success, long-felt need, unexpected results, failure by others (including Hlavka), skepticism, and (extensive) copying by others, which confirm that selecting PEG as the cryoprotectant or using an antioxidant in an FMT formulation packaged as a ready-to-use enema was not an obvious choice. *See, e.g.*, 08/06/24 Trial Tr. 18:2-17 (long-felt need); PTX-805 (OpenBiome license); PTX-427. Indeed, Ed Hlavka, the inventor of the sole prior art reference Ferring relies on to show obviousness, expressed surprise that PEG was effective as a cryoprotectant for fecal bacteria. 08/07/24 Trial Tr. at 136:25-139:4.

2. Claims 2 and 9 of the '080 Patent Are Valid.

No reasonable juror could find claims 2 and 9 of the '080 patent would have been obvious over Hlavka for at least the reasons discussed above. Furthermore, as to claim 2, which requires that the system protect the composition "when the sealed container is exposed to air," Ferring's expert, Dr. Britton, conceded that Hlavka does not disclose an antioxidant, yet Dr. Britton was unable to identify any other element or Hlavka (or any other prior art reference) that would protect the composition when exposed, further evidencing the non-obviousness of claim 2. *See* 08/07/24 Trial Tr. at 280:3-281:18.

3. Claim 7 of the '914 Patent Is Valid.

Based on the evidence adduced at trial, no reasonable juror could find that claim 7 of the '914 is invalid under 35 U.S.C. § 112. The evidence confirmed that, contrary to Ferring's only invalidity arguments the specification provides more than sufficient written description for the "relative abundance" limitation, which requires that the administration of the claimed pharmaceutical composition reduce "the relative abundance of one or more members of the phylum Proteobacteria … by at least 10%," and the claimed Markush group, which requires the composition include at least six of ten identified classes of bacteria. *See* '914 Patent, cl. 4.

Section 112 "require[s] only sufficient description to show one of skill … that the inventor possessed the claimed invention at the time of filing." *Union Oil Co. of California v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006). Indeed, "the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before." *Id.* "Placed in that context, it is unnecessary to spell out every detail of the invention in the specification." *Id.*

Given the '914 Patent's disclosures, no reasonable juror could find by clear and convincing evidence that the inventors of the '914 Patent did not possess a composition that reduced proteobacteria by at least 10%. *See, e.g.*, *id.* Example 1 of the '914 patent, which is an embodiment of claim 7, describes the results of the inventors' sequencing analysis depicted in Figures 1 and 2 and describes a change in the patient's microbiota post-transplantation, as confirmed by the clustering in Figure 3 and the text provided with Example 1. For example, the '914 Patent discloses that prior to the administration of the claimed composition, patient data showed the gut microbiome included "greater than 40% mollicutes or Gammaproteobacteria," whereas, after administration, it was "dominated by Firmucites," indicating that the relative abundance of gammaproteobacteria was significantly reduced. '914 Patent at 17:21-26; *see also id.* at 17:35-39 (noting the bacteria taxa present pre- and post-administration "differed considerably, suggesting that fecal bacteriotherapy was success in altering the patient's intentional microflora). As Dr. Khoruts explained, the text accompanying figure 1 confirms that the inventors were in possession of a stool composition that reduces proteobacteria by 10%. 08/05/24 Trial Tr. 155:12-158:17; *see also* JTX-1.20, .21, .25; 08/05/24 Trial Tr. at 194:15-24.

Ferring, however, argues that a POSA would be unable to discern from Figure 1 whether the inventors were in possession of a stool composition that had six of the ten recited classes of bacteria wherein the proteobacteria was decreased by at least 10% because those figures are in black and white. Ferring's expert, Dr. Treangen, is undisputedly not a POSA and his opinions regarding the '914 Patent's written disclosures, which must be read from the perspective of a POSA, are therefore legally inadequate. *See Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1377-78 (Fed. Cir. 2022) (holding it is an abuse of discretion to admit testimony from a non-POSA "on any issue that is analyzed through the lens of an ordinarily skilled artisan"); 08/07/24 Trial Tr. 237:20-238:20. But even Dr. Treangen confirmed that a study he was

involved in found that 95% of study participants' stool had six of the ten recited classes of bacteria. 08/07/24 Trial Tr. 239:21-240:6; 08/05/24 Tr. at 185:14-16 (Sadowsky testimony).

Moreover, Example 4 describes a similar study as Example 1 but involving more patients and describes similar results, including the successful treatment of rCDI in 95% of the patients involved. '914 Patent at 25:46-26:33; 08/05/24 Trial Tr. at 172:2-24 (describing patient population). And as Dr. Sadowsky testified, the successful treatment of patients with rCDI in and of itself indicates a reduction of proteobacteria of at least 10%. 08/05/24 Trial Tr. at 194:15-24; JTX-1(Tbl.3). The '914 Patent's specification thus spells out sufficient detail "to convince a person of skill in the art that the inventor possessed the invention." *Falko-Gunter*, 448 F.3d at 1366. Ferring resorts to criticizing the inventors' work simply because the patent office prints patent figures in black and white. But even Dr. Treangen agreed that there is no dispute the figures in Example 1 are based on data. 08/07/24 Trial Tr. 240:18-241:21.

F. UMN/Finch Are Entitled to Damages

UMN/Finch are statutorily entitled to no less than a reasonable royalty for every infringing sale or action by Ferring. 35 U.S.C. § 284; *Dow Chem. Co. v. Mee Indus., Inc.*, 341 F.3d 1370, 1381 (Fed. Cir. 2003) ("The statute is unequivocal that the district court must award damages in an amount no less than a reasonable royalty."). No reasonable jury could find (1) that the required royalty is anything other than an upfront payment and running royalty, or (2) that the upfront payment would be less than $50 million or the running royalty rate less than 30%. UMN/Finch are accordingly entitled as a matter of law to $54.4 million in damages for Ferring's infringing conduct from the date of first infringement to the present.

This damages award is supported by the testimony of Mr. Malackowski and Mr. Burgess. Mr. Malackowski relied on Finch's technical expert, Dr. Benson, to identify the technologically comparable license, *see* 08/06/24 Trial Tr. at 104:7-105:4, and then considered those agreements,

found the relevant economic data points, and applied the *Georgia-Pacific* factors to calculate the appropriate royalties. 08/06/24 Trial Tr. at 178:6-11, 181:21-195:2, 198:8-205:12. Based on those considerations and reasonable estimates of REBYOTA's expected revenue over the lifetime of the patents and the harm suffered by Finch as a result of Ferring's infringement, Mr. Malackowski determined that in a hypothetical negotiation as of November 30, 2022, the parties would have conservatively arrived at a lump-sum upfront payment of $50 million, with a running reasonable royalty rate of 30%. *Id.* at 205:15-210:6; *see also id.* at 133:2-142:25 (Finch's co-founder, James Burgess', testimony regarding the impact of Ferring's infringement on Finch and comparable Finch licensing agreements); PTX-365, PTX-366, PTX-805, PTX-817 (comparable licenses and license offers); PTX-731A.2 (Ferring annual and projected annual revenue).

No reasonable jury could credit Ferring's arguments for a lower damages number. Ferring's expert, Dr. Kidder, failed to take into account the relevant licenses or industry practices, all of which point in the same direction and support Mr. Malackowski's conclusion that the parties would have negotiated a reasonable royalty with an upfront payment and royalty rate of at least 30%. Similarly, Dr. Kidder ignored the facts of the case showing the parties' relative positions at the hypothetical negotiation, including at least Ferring's projections that REBYOTA would generate over $2.1 billion in sales over the life of the patents.

IV. CONCLUSION

For the foregoing reasons, the Court should grant UMN/Finch's motion for judgment as a matter of law.

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Dated: August 8, 2024

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